IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
GREENVILLE DIVISION

ESTATE OF DORIS BURNETT,
Deceased, By and Through the
Administrator, MONIQUE BURNETT,

PLAINTIFF

vs. **CIVIL ACTION NO. 4:08-CV-00026-WAP-EMB**

Pending Transfer to MDL-1699
(In re Bextra and Celebrex Marketing,
Sales Practices and Products
Liability Litigation)

PFIZER, INC.,

DEFENDANT

DEFENDANT'S ANSWER AND DEFENSES TO PLAINTIFF'S COMPLAINT

NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer" or "Defendant"), and files its Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
ORIGINAL ANSWER

Response to Allegations Regarding Parties

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff is the Administrator of Decedent's Estate, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

2. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's relationship to Decedent, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

3. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff is the Administrator of Decedent's Estate and whether Plaintiff has standing to bring this suit, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and place of residence, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

5. Defendant admits that it is a Delaware corporation with its principal place of business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

6. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® (valdecoxib) ("Bextra®") in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

7. Defendant admits that Pharmacia & Upjohn Company LLC ("Pharmacia & Upjohn") is a subsidiary of Pfizer. Defendant denies the remaining allegations in this paragraph of the Complaint.

8. Defendant denies that Pharmacia & Upjohn ever designed, produced, manufactured, marketed, sold, resold or distributed Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint. The response to this paragraph of the Complaint regarding Pharmacia & Upjohn is incorporated by reference in response to each paragraph of the Complaint referring to Pharmacia & Upjohn.

9. Defendant admits Searle LLC ("Searle") is a subsidiary of Pfizer. Defendant denies the remaining allegations in this paragraph of the Complaint.

10. Defendant admits that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in

the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

11. Defendant admits that, as the result of a merger in April 2003, Searle became a subsidiary of Pfizer. Defendant denies the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

12. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, denies that the same. However, Defendant admits that Plaintiff claims that the amount in controversy exceeds $75,000, exclusive of interests and costs.

13. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint, and, therefore, denies the same.

Response to Statement of Facts

14. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Decedent's medical condition, Decedent's date of death, and whether Decedent used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

15. Defendant states that, as stated in the FDA-approved labeling for Bextra®, "[t]he mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-2). At therapeutic plasma concentrations in humans valdecoxib does not inhibit cyclooxygenase-1 (COX-1)." Defendant admits that, as indicated in the package insert approved by the FDA, Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.

16. Defendant states that, as stated in the FDA-approved labeling for Bextra®, "[t]he mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily

through inhibition of cyclooxygenase-2 (COX-2). At therapeutic plasma concentrations in humans valdecoxib does not inhibit cyclooxygenase-1 (COX-1)." Defendant denies the remaining allegations in this paragraph of the Complaint.

17. Defendant admits that Bextra® was approved by the FDA on November 16, 2001. Defendant admits that, as indicated in the package insert approved by the FDA, Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.

18. Defendant states that the referenced study speaks for itself and respectfully refers the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendant denies the remaining allegations in this paragraph of the Complaint.

19. Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding parecoxib. Defendant is therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

20. Plaintiff fails to provide the proper context for the allegations concerning parecoxib in this paragraph of the Complaint. Defendant is therefore without knowledge or information sufficient to confirm or deny such allegations, and, therefore, denies the same. Defendant states that the Bextra® label speaks for itself and respectfully refers the Court to the Bextra® label for its actual language and full text. Any attempt to characterize the Bextra® label is denied. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

21. Defendant states that the referenced study speaks for itself and respectfully refers the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendant denies the remaining allegations in this paragraph of the Complaint.

22. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

23. Defendant admits that a labeling revision for Bextra® was implemented on December 9, 2004. Defendant states that the revised Bextra® label speaks for itself and respectfully refers the Court to the revised Bextra® label for its actual language and full text. Any attempt to characterize the revised Bextra® label is denied. Defendant denies the remaining allegations in this paragraph of the Complaint.

24. Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding "other COX-2 inhibitor drug use." Defendant is therefore without knowledge or information sufficient to confirm or deny such allegations, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies the remaining allegations in this paragraph of the Complaint.

25. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

26. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

27. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

28. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

29. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

30. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

31. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant admits that the sale of Bextra® was voluntarily

suspended in the United States market as of April 7, 2005. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

32. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

33. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Strict Liability

34. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

35. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers

without substantial change from the time of sale. Defendant denies the remaining allegations in this paragraph of the Complaint.

36. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

37. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

38. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

39. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

40. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which

was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

41. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

42. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 42 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Negligence

43. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

44. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times

adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

45. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

46. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

47. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

48. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

49. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 49 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Negligence Per Se

50. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

51. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

52. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent a response is deemed required, Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

53. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent a response is deemed required, Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

54. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent a response is deemed required, Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

55. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent a response is deemed required, Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

56. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

57. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

58. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused

Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

59. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 59 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Express Warranty

60. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

61. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

62. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

63. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

64. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

65. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 65 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Breach of Implied Warranty

66. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

67. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff or Decedent used Bextra®, and, therefore, denies the same. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant states that Bextra® was and is safe and

effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

68. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Decedent used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

69. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

70. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

71. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

72. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of

Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 72 of the Complaint, Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff or Decedent injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Jury Trial Request

73. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required.

II.
GENERAL DENIAL

Defendant denies the allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

III.
AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon

which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendant.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendant are barred to the extent Decedent was contributorily negligent, actively negligent or otherwise failed to mitigate Decedent's damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff or Decedent were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendant affirmatively denies that it violated any duty owed to Plaintiff or Decedent.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Decedent's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Decedent was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendant and any liability of Defendant is therefore barred.

Seventeenth Defense

17. Plaintiff's and Decedent's alleged injuries/damages were not caused by any failure to warn on the part of Defendant.

Eighteenth Defense

18. Plaintiff's and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Decedent knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages would violate Defendant's rights to procedural due process under the Fourteenth Amendment of the United States Constitution and Constitution of the State of Mississippi, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution and the Constitution of the State of Mississippi.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiff and Decedent failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and,

therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitution of the State of Mississippi. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff and Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff or Decedent sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Decedent's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Decedent, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff or Decedent.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff and Decedent did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Decedent would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff and Decedent.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff's claims are barred because Defendant did not make or breach any express or implied warranties, Plaintiff and Decedent failed to give reasonable notice to Defendant of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

Fifty-sixth Defense

56. Any verdict or judgment rendered against Defendant must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiff or Decedent, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiff or Decedent may have settled the claims

for alleged injuries and damages with certain parties. Defendant therefore is, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiff or Decedent and any such parties.

Fifty-seventh Defense

57. Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

Fifty-eighth Defense

58. Defendant asserts that Plaintiff's claim for punitive damages is governed and limited by Miss. Code Ann. § 11-1-65, and Defendant hereby pleads and invokes the provisions of the same.

Fifty-ninth Defense

59. Bextra® and the Defendant's actions conformed to the state of the art medical and scientific knowledge at all times relevant to this lawsuit and/or Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

Sixtieth Defense

60. Defendant satisfied its duty to warn under the learned intermediary doctrine and Plaintiff's claims are therefore barred.

Sixty-first Defense

61. Defendant hereby pleads all defenses contained in Miss. Code Ann. § 11-1-63 and hereby invokes the provisions of Miss. Code Ann. § 85-5-7.

Sixty-second Defense

62. Plaintiff failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to Defendant in any possible future litigation.

Sixty-third Defense

63. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to warn, are unconstitutional in that, among other things, they are void for vagueness and undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

Sixty-fourth Defense

64. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendant, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any award of punitive damages is barred.

Sixty-fifth Defense

65. Plaintiff's claims are barred in whole or in part because Plaintiff lacks standing to bring such claims.

Sixty-sixth Defense

66. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

IV.
JURY DEMAND

Defendant hereby demands a trial by jury.

V.

PRAYER

WHEREFORE, Defendant prays that Plaintiff takes nothing by this suit; that Defendant be discharged with its costs expended in this matter, and for such other and further relief to which it may be justly entitled.

This 20th day of June, 2008.

Respectfully submitted,

By: /s/ Walter T. Johnson
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ATTORNEYS FOR DEFENDANT
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CERTIFICATE OF SERVICE

I hereby certify that on June 20, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF system which sent notification of such filing to the following:

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ATTORNEYS FOR PLAINTIFF

/s/ Walter T. Johnson
Walter T. Johnson